

### **REMARKS**

Claims 1-64 and 71-78 are all the pending claims in the application. Claims 1-11 and 13-64 are withdrawn from examination. Claims 12 and 71-78 are all the pending claims under examination for this application. Claims 12, 71-72, and 74-77 are cancelled without prejudice. Claims 73 and 78, the remaining pending claims under examination, are amended. Support for the amendment can be found throughout the specification, for example, in Example 1. No new matter is added by the amendment.

#### **Rejections under 35 USC Section 112, 1<sup>st</sup> Paragraph:**

The Office Action has rejected claims 73-76 and 78 under 35 U.S.C. 112, first paragraph, for allegedly not being enabled by the specification, and further for being indefinite. Specifically, the Office Action asserts that the only cell line for which the method is enabled is using the LNCaP-FGC cell line, and that one of skill in the art would not know how long the experiment should be carried out.

Applicant respectfully disagrees. However, purely to progress the prosecution of the instant application, Applicant has cancelled claims 74-76, and limited pending claims 73 and 78 to the use of LNCaP-FGC cells which has been stated in the Office Action to be enabled.

Further, Applicant has amended the claims as set forth above to recite that the cells are cultured in the presence of a compound, and suppression of proliferation for 6 weeks or 13 weeks is an indication that the compound does not induce antiandrogen drug resistance. This provides a definite time at which when proliferation is not observed, an antiandrogen drug can be identified as a drug that does not induce antiandrogen drug-resistance. As noted in the Office Action, one of skill in the art would be a "drug discovery technologist with a background in screening anti-hormone response drug therapy for cancer". Applicant submits that such a person would have at least doctoral level training, if not post-doctoral level training. One of skill in the art would understand that after determining that a compound was, or was not, a drug that does not induce anti-androgen drug resistance that the experiment could be terminated.

Applicant submits that one of such high skill in the art would understand when an experiment should be terminated. As discussed in the prior response, if the cells proliferate prior to 6 weeks or 13 weeks, the compounds induce resistance, and there is no need to continue the experiment. The samples can be discarded. If the cells die before 6 weeks or 13 weeks, the cells will never proliferate. The samples can be discarded. If the cells when observed at 6 weeks or 13 weeks are viable, i.e., have the potential to proliferate, but have not proliferated, the compounds are identified as compounds that do not induce resistance.

Although drawn to a different method of screening, Applicant points to US Patent 7,312,047 which provides a method of screening a test agent for ability to improve barrier function of epithelium formed. Claim 1 is reproduced below:

1. A method of screening a test agent for ability to improve barrier function of epithelium formed from cultured asthmatic bronchial epithelial cells, which comprises: (i) providing cultured asthmatic bronchial epithelial cells; (ii) further culturing said cells on a porous support at an air-liquid interface whereby they differentiate in culture and will form an in vitro epithelium, said culturing being in the absence of any added Th2 or proinflammatory cytokine and for a period such that an epithelial barrier is detectable; (iii) adding to the culture, either at the start of culturing or during culturing said test agent whereby the test agent is contacted with the epithelial cells; (iv) and determining at one or more time points after formation of an epithelial barrier is detectable whether said test agent improves epithelial barrier function compared with epithelial barrier function detectable in an identical culture without the test agent. [emphasis added]

As the claim is allowed, it is presumed to be valid, and therefore definite. Applicant submits that although the specific field of screening is different, the level of one of skill in the art would be the same for the instantly claimed invention and the invention of the '047 patent. One of skill in the art would find the above claim to be definite just as one would find the instantly pending claims to be definite.

Applicant submits that the claims are fully supported by the specification and definite. Withdrawal of the rejection is respectfully requested.

2. Rejection under 35 USC Section 103

The Office Action has rejected claims 12, 71, 72 and 77 under 35 U.S.C. §103(a) as allegedly being unpatentable over Long et al (Can. Res. 60:6630-6640 (2000); cited in the PTO 892 form of 5/15/07) in view of Culig et al. ((Br. J. Can. 81:242-251 (1999); cited in the PTO 892 form of 1/12/07) and Haapala et al., Lab. Invest., 81: 1647-1651, 2001); cited in the IDS of 12/2/04).

Applicant respectfully disagrees. However, purely to progress the prosecution of the application, Applicant has amended the claims as set forth above to cancel claims 12, 71, 72 and 77. The rejection is moot.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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